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**Remarks**

**Rejections**

**Obviousness-type Double Patenting**

Claims 1-7, 14 and 24-36 have been provisionally rejected under the doctrine of obviousness-type double patenting over US Application 09/885568.

**35 U.S.C. §102(b)**

Claims 1-2, 12-14, 19 and 24 have been rejected under 35 U.S.C. §102(b) as being anticipated by Rau et al. (WO 95/18647).

The Office Action asserts that Rau et al. has a balloon catheter (col. 1, lines 1-5) which can be of integral catheter shaft/balloon construction (col. 14, lines 1-5) comprising a plurality of fibers to provide reinforcement (col. 8, lines 55-65).

Claim 1 has been amended to recite a polymer matrix component comprising specific polymers which are not suggested by Rau et al. for use in making polymer balloons.

Support for the amendment to claim 1 is found in US 6,242,063 (Serial No. 08/926,905) and US 6,284,333 (Serial No. 08/257,677), both of which are incorporated by reference on page 2, lines 1-6 of the specification.

Support from US 6,242,063 is found at column 4, lines 30-50 and support from US 6,284,333 is found at col. 2, lines 10-37.

Support may also be found from page 5, lines 16-19 of the present specification.

No new matter has been added.

Applicants assert that Rau et al. describe the incorporation of thermoplastic polyimide into various parts of balloon catheters such as catheter shafts and balloons (Abstract), and do not suggest other polymer materials for use in the formation of a balloon. See col. 3, lines 58-67 and col. 4, lines 1-6).

Claims 2, 12-14, 19 and 24 depend from claim 1 and are patentable for at least the reasons that claim 1 is patentable.

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Based on the foregoing, Applicants respectfully request withdrawal of the rejection of claims 1-2, 12-14, 19 and 24 under 35 U.S.C. §102(b) as being anticipated by Rau et al.

**35 U.S.C. §103(a)**

Claims 31, 33 and 36 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Rau et al. (WO 95/18647). The Office Action asserts that Rau et al. teaches the dimensionally stable balloon having a longitudinal axis and composed of a micro-composite material comprising a polymer matrix component and a liquid crystal polymer fibril component distributed in the polymer matrix component, the fibril component having micro-fibers oriented substantially parallel to the longitudinal axis of the balloon.

Applicants traverse the rejection.

Claim 31 is directed to an embodiment of the invention in which the matrix material is characterized as being semi-compliant.

Rau et al. discloses the incorporation of thermoplastic polyimide into various parts of balloon catheters such as catheter shafts and balloons.

Polyimides, being relatively inelastic and hard materials, are non-compliant polymeric materials. Applicants have enclosed a summary of physical properties for polyimide, available online from MatWeb, a copy of which is enclosed herewith. Compliance of balloon materials is discussed, for example, in commonly assigned U.S. Patent No. 5,556,383, a copy of which is enclosed herewith.

The elongation at break for polyimide as found on page 2 of the polyimide overview is 4-10%. The hardness of polyimide, as measured using the Rockwell E hardness scale, is 50-99. The Rockwell hardness scales are employed for metals and for otherwise very hard materials while the Shore hardness scales are employed for polymeric materials. Applicants have included a summary from a website, <http://www.machinist-materials.com/hardness.html>, which shows a comparison of the various scales.

The properties of polyimide may be compared to polyethylene terephthalate, a non-compliant material, which has an elongation of 50% to 350% and a

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Rockwell Hardness of 110. A data sheet available online from MatWeb, has been enclosed herewith. See also commonly assigned U.S. Patent No. 5,556,383, enclosed herewith.

Consequently, claim 31 is not obvious over Rau et al. because a semi-compliant material has properties which are quite different from those of polyimide. Consequently, the balloon properties obtained from using a semi-compliant matrix material could not be predicted from the teachings of Rau et al.

Claims 33 and 36 depend from claim 31 and are patentable for at least the reasons that claim 31 is patentable.

Applicants respectfully request withdrawal of the rejection of claims 31, 33 and 36 under 35 U.S.C. §103(a) as obvious over Rau et al., WO 95/18647.

Claims 3-8, 25 and 26 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Rau et al. as applied to claims 31, 33 and 36 above, and further in view of Zdrahala (previously cited US 5,248,305).

Claim 1 has been amended as discussed above to recite a polymer matrix component comprising specific polymers not taught by Rau et al.

Rau et al. has been discussed above and describes the incorporation of thermoplastic polyimide into catheter shafts and balloons. Rau et al. do not teach the incorporation of any other polymer materials into a balloon.

Zdrahala describes extruded catheters and other flexible plastic tubing with improved rotational and/or longitudinal stiffness, compared with catheters made of more conventional plastics. A tubing of liquid crystal polymer plastic-containing material may be extruded through a tube extrusion die while rotating the inner and outer die walls to provide circumferential shear to the extruded tube. Thus the liquid crystal polymer is oriented in a helical manner to provide improved properties, including greater rotational stiffness (Abstract).

Zdrahala is directed to tubing only, however, and not to the formation of balloons.

Consequently, combining Zdrahala with Rau et al. does not lead one of skill in the art to the invention of claim 1.

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Claims 3-8 and 25-26 depend from claim 1 and are patentable for at least the reasons that claim 1 is patentable.

Applicants respectfully request withdrawal of the rejection of claims 3-8 and 25-26 under 35 U.S.C. §103(a) as being obvious over Rau et al. WO 95/18647 in view of Zdrahala, US 5,248,305.

Claims 15-18 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Rau et al. as applied to claims 31, 33 and 36, above, and further in view of Zdrahala (previously cited US 5,248,305) as evidenced by Yang (previously cited Polymer Data Handbook).

Rau et al. and Zdrahala have been discussed above.

The Office Action employs Yang to show that hydroxypropylcellulose has a melting point of 208°C.

Claim 1 is patentable over Rau et al. and Zdrahala as discussed above. Combining Rau et al. and Zdrahala with Yang, does not lead one of skill in the art to the invention of claim 1.

Claims 15-18 depend from claim 1 and are patentable for at least the reasons that claim 1 is patentable.

Claims 20 and 22-23 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Rau et al. as applied to claims 31, 33 and 36, above, and further in view of Zdrahala (previously cited US 5,248,305) as evidenced by Polymers (previously cited A Property Database).

Rau et al. and Zdrahala have been discussed above.

Claim 1 is patentable over Rau et al. and Zdrahala as discussed above.

Polymers is employed by the Examiner to show that nylon has a melting point range of from 169°C to 187°C which is within the claimed range of about 140°C to, 265°C (claim 20), the claimed range of about 150°C to 230°C (claim 22) and the claimed range of about 220°C or less (claim 23).

Combining Polymers with Rau et al. and Zdrahala does not lead one of skill in the art to the invention of claim 1.

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Claims 20 and 22-23 depend from claim 1 and are patentable for at least the reasons that claim 1 is patentable.

Applicants respectfully request withdrawal of the rejection of claims 20 and 22-23 under 35 U.S.C. §103(a) as being unpatentable over Rau et al. as applied to claims 31, 33 and 36, above, and further in view of Zdrahala (previously cited US 5,248,305) as evidenced by Polymers (previously cited A Property Database).

Claim 21 is rejected under 35 U.S.C. §103(a) as being unpatentable over Rau et al. in view of Zdrahala (previously cited US 5,248,305) as applied to claims 31, 33 and 36, above, as evidenced by Alger (previously cited Polymer Science Dictionary).

Rau et al. and Zdrahala have been discussed above.

The Office Action asserts that Zdrahala teaches a polyester-polyether block copolymer such as HYTREL for the catheter tubing matrix material, and that Alger defines HYTREL as a polyether-polyester block copolymer (page 255).

Claim 1 is patentable over Rau et al. and Zdrahala for the reasons presented above. As discussed above, Zdrahala describes extruded catheters and other flexible plastic *tubing* manufactured by extruding a tube of liquid crystal polymer plastic-containing material through a tube extrusion die. Zdrahala describes *tubing* only, and does not suggest further processing of the tubing to form balloons.

Thus, combining Zdrahala and Alger with Rau et al., does not lead one of skill in the art to claim 1 as amended. Claim 21 depends from claim 1 and is patentable for at least the reasons that claim 1 is patentable.

Applicants respectfully request withdrawal of the rejection of claim 21 under 35 U.S.C. §103(a) as being unpatentable over Rau et al. in view of Zdrahala (previously cited US 5,248,305) as applied to claims 31, 33 and 36, above, as evidenced by Alger (previously cited Polymer Science Dictionary).

Claims 8-11 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Rau et al. as applied to claims 31, 33 and 36 above, and further in view of Heino et al. (previously cited US 6,221,962).

The Office Action asserts that Rau et al. teaches the dimensionally stable balloon having a longitudinal axis and composed of a micro-composite material, the

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micro-composite material comprising a polymer matrix component and a liquid crystal polymer fibril component distributed in the polymer matrix component, the fibril component having micro-fibers oriented substantially parallel to the longitudinal axis of the balloon, but fails to teach a compatilizer component in the micro-composite material. The Office Action asserts that Heino et al. is directed to LCP blends wherein the LCP polymer forms fibers which orient in the flow direction of the thermoplastic matrix melt, improving the tensile strength and modulus of elasticity of the solidified matrix (col. 1, lines 30-35). The compatibilizer can be a block copolymer (col. 3, lines 1-15 and claim 9), an example of which is ethyl acrylate-ethylenc-glycidyl methacrylate (col. 7, lines 55-60 and claims 10-11).

Applicants have discussed Rau et al. above.

Claim 1, as amended, is different from Rau et al. for the reasons discussed above.

Applicants assert that Heino et al. describe a polymer blend containing 95 to 50 parts by weight of a polyolefin- or polyester-based polymer matrix, 5 to 50 parts by weight of an aromatic main-chain liquid crystalline polymer and plastic additives, if any. Further, the blend contains, based on the total weight of the previous components, 0.1 to 30 percent by weight of a substance (a compatibilizer) which improves the compatibility of the polymer matrix and the liquid crystalline component. The compatibilizer includes a polymer containing reactive functional groups. Preferably, the compatibilizer includes an SEBS polymer functionalized with maleic anhydride or an olefin polymer functionalized with glycidyl methacrylate (Abstract).

Heino et al. fail to teach that the blend can be employed for use in the formation of balloons.

Rau et al. teach the incorporation of thermoplastic polyimide in catheter shafts and balloons.

There would be no motivation to substitute the blends of Heino et al. in the balloons of Rau et al., as it would defeat the primary purpose of Rau et al., which is the incorporation of thermoplastic polyimide.

Thus, claim 1 is patentable over Rau et al. in view of Heino et al.

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Claims 8-11 depend from claim 1 and are patentable for at least the reasons that claim 1 is patentable.

Applicants respectfully request withdrawal of the rejection of claim 8-11 under 35 U.S.C. §103(a) as being unpatentable over Rau et al. as applied to claims 31, 33 and 36 above, and further in view of Heino et al. (previously cited US 6,221,962).

### CONCLUSION

Claims 1-26, 31, 33 and 36 are pending in the application. Applicants have addressed each of the issues presented in the Office Action. Based on the foregoing amendments and arguments, Applicants respectfully request reconsideration and an early allowance of the claims as presented. Should any issues remain, the attorney of record may be contacted at (952)563-3011, to expedite prosecution of this application.

Respectfully submitted,

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*July 28, 2004*

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